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TITLE: Determining Clinically Relevant Changes in Community Walking Metrics to Be Tracked by the VA as Part of Routine Care in Lower Limb Amputee Veterans

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| 13. SUPPLEMENTARY NOTES | | | | | |
| 14. ABSTRACT The objective of this study is to define clinically meaningful change in the walking function of lower limb prosthetic users in order to more easily assess whether a patient is improving or declining in function over time. However, little is known about the natural fluctuations in walking metrics from week to week when walking function is stable versus clinically relevant changes in walking function. Therefore, it will be important to define meaningful change in walking function when interpreting the impact of prosthetic components, rehabilitation, and other treatments on real world walking. Recruitment has been completed and data collection is near completed. A total of 100 subjects have enrolled in the study: Veteran subjects n=55 and University of Utah subjects n=45. Preliminary analysis indicates that daily steps and distance walked may track most closely to perceived change in walking function. However, data collection is on-going and necessary before cut points that represent meaningful change is recommended. | | | | | |
| 15. SUBJECT TERMS walking, ambulation, lower limb prosthesis, function, clinically relevant change | | | | | |
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INTRODUCTION

The objective of this study is to determine clinically meaningful change in the community walking metrics to be tracked by the VA as part of the new VA initiative. The metrics are the following: 1) functional level assessment, 2) peak performance index, 3) daily steps, 4) walking distance, 5) cadence, and 6) cadence variability. The specific aims are 1) to determine small meaningful change in the community metrics and 2) to determine substantial meaningful change in the community metrics. The sensitivity and specificity of each cut-point value representing small and substantial change will also be reported.

This study will require the recruitment of 100 research participants that ambulate with a lower limb prosthesis. Participants will be recruited from the Salt Lake City VA Medical Center and the University of Utah amputee clinic. The StepWatch activity monitor will be attached to the prosthesis and provide weekly reports on the participant's community walking metrics. Clinically relevant change will be based on participant reported Global Mobility Change Rating score for each week. Each participant will be monitored for six months. A diagnostic testing framework will be used to find the optimal cut-points on the community metrics, which maximizes classification accuracy (no change, small meaningful change, or substantial meaningful change).

KEYWORDS

Ambulation, walking, function, lower limb prosthesis, veteran, clinically relevant change

ACCOMPLISHMENTS

What were the major goals of the project?

| Specific Aims: 1) to determine small and 2) substantial meaningful change in the community walking metrics | Timeline | Status |
|---|-----------------|---------------|
| Major Task 1: Human Subject Research Approval | Months | |
| <i>Milestone #1: Achieve IRB and USAMRMC ORP HRPO Approval</i> | 3 | Completed |
| Major Task 2: Data Collection | | |
| <i>Milestone #2: Complete data collection (n=100)</i> | 22 | 99% Completed |
| Major Task 3: Data Analysis | | |
| <i>Milestone #3: Complete Data Analysis</i> | 23 | 50% Completed |
| Major Task 4: Reporting / Data Sharing | | |
| <i>Milestone #4: Reporting requirements and data sharing protocols completed</i> | 24 | 20% Completed |

What was accomplished under these goals?

Human subject approvals were obtained and n=100 subjects have enrolled. Data collection is complete on 93 out of the 100 subjects. Activities included recruiting and consenting 100 subjects, programming StepWatches, placing StepWatches on prostheses, collection of weekly Global Mobility Change Rating scores, mailing StepWatches weekly, and receiving / downloading Stepwatches weekly. Dr. Godfrey has edited the monthly StepWatch files into 1,100 weekly reports to date, and Dr. Chou has reviewed 408 of these weekly reports and added them to the spreadsheet for statistical analysis. Another preliminary statistical analysis is underway.

What opportunities for training and professional development have the project provided?

This project has included two medical residents training in the rehabilitation field. One has remained active for the last year by assisting with followup phone calls to patients and will be using preliminary data for an upcoming abstract submission for a prosthetic conference or the Association of Academic Physiatrists annual conference. The other presented a poster presentation at the Association of Academic Physiatrists annual conference in Las Vegas. They are receiving value research and technical writing experience.

How were the results disseminated to communities of interest?

A poster presentation was presented at the Association of Academic Physiatrist Annual meeting in Las Vegas, NV by a resident. The title was Community Functional Walking Metrics, a Preliminary Report. A key finding was that an increase in 99 steps per day was associated with a 1 unit increase in the Global Mobility Rating Score.

What do you plan to do during the next reporting period to accomplish the goals?

During the next reporting period, I intend to complete data collection, data processing, and data analysis. A manuscript will be prepared for submission of this study and results will be posted on our website.

IMPACT

What was the impact on the development of the principal discipline(s) of the project?

The project is creating a data rich dataset that can be used to address other research questions. For example, new community walking metrics can be created and analyzed using the files already collected on subjects. Also, sub analyses can be performed to determine if new prosthetic components or therapies appear to result in increased walking at home. This allows further learning without the expense of recruiting new subjects.

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

CHANGES/PROBLEMS

Changes in approach and reasons for change

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

Data processing was taking longer than anticipated. To resolve the problem, we obtained a no cost extension.

Changes that had a significant impact on expenditures

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

PRODUCTS

Nothing to report

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Provide the name and identify the role the person played in the project

| Name | Project Role | Research Identifier | Person month worked | Contribution to project | Funding support |
|----------------|--------------|---------------------|---------------------|--|-----------------|
| Teri Chou, PhD | PI | 0000-0001-8401-2938 | 2 | Overview of project, data processing, patient recruitment, data processing, data | N/A |

| | | | | | |
|----------------------|---|-----|---|---|-----|
| | | | | entry, and statistical overview | |
| Bradeigh Godfrey, DO | Subcontract PI (WIBR at the SLC VA Hospital) | N/A | 2 | Patient recruitment, data download, mailing stepwatches, recruitment of medical residents, and data processing | N/A |
| Chris Duncan, MD | Investigator (physician at WIBR at the SLC VA Hospital and University of Utah | N/A | 1 | Patient recruitment, data download, mailing stepwatches, recruitment of medical residents, and manuscript drafting. | N/A |
| Jacob Smith, MS | Study coordinator | N/A | 3 | Interfacing with IRB, patient recruitment, weekly subject survey calls, overseeing mailing of stepwatches, and subject payment. | N/A |

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Nothing to Report

SPECIAL REPORTING REQUIREMENTS

The Quad Chart is in the appendix

APPENDICES

Determining clinically relevant changes in community walking metrics to be tracked by the VA as part of routine care in lower limb amputee veterans

Log No: OP140008

PI: Teri Chou, PhD

Org: Modus Health LLC

Award Amount: \$465,470



Study/Product Aim(s)

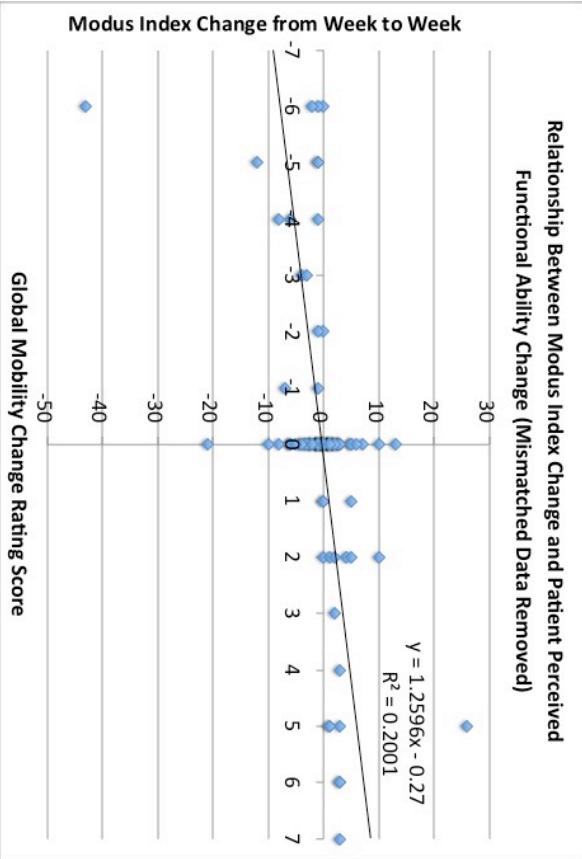
- To determine the magnitude of clinically relevant change in the community walking metrics to be tracked by the VA in veteran lower limb prosthetic users.

Approach

A sample size of n=100 Veteran and University of Utah patients that use lower limb prostheses will be recruited. Each participant will receive a StepWatch on their prosthetic limb for tracking community metrics for six months (Figure 1). An email or phone survey will be used for collecting weekly responses to the Global Mobility Change Rating scale for determining small and substantial meaningful change. Data will be analyzed to determine each metrics small and substantial change thresholds and the associated sensitivity and specificity for these thresholds.

Timeline and Cost

| Activities | CY | 15/16 | 16 | 16/17 | 17/18 |
|---------------------------|----|-------|--------|-------|--------|
| IRB Approval | | | | | |
| Data Collection | | | | | |
| Analyze Results | | | | | |
| Reporting / Data Sharing | | | | | |
| Estimated Budget (\$465K) | | | \$276K | | \$189K |



Graph illustrating preliminary findings used in abstract (n=28)

Goals/Milestones

CY15 Goal – IRB Approval

- ☒ Prepare/Submit IRB application
- ☒ Obtain IRB approval

☒ Obtain HRPO regulatory approval

CY16 Goal – Recruitment and Data Collection

☒ Recruit/Collect Data n=80 subjects

CY17 Goal – Recruitment, Data Collection, Analyze Results, Reporting, Data Sharing

- ☐ Complete recruitment and data collection on n=100 subjects
- ☐ Complete data entry and data cleaning procedures
- ☐ Complete statistical analysis
- ☐ Provide Quarterly reports to USAMRAA
- ☐ Share data results on Modus Health LLC website
- ☐ Prepare manuscript for JRRD submission

Comments/Challenges/Issues/Concerns

Timeline increased b/c of no cost extension

Budget Expenditure to Date

Projected Expenditure: \$350K Actual Expenditure: \$340K